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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/900,559 07/25/97 CHENG

S 226/242

022249
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HM12/0327

EXAMINER

HINES, J

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/900,559

Applicant(s)
Cheng et al.

Examiner
Ja-Na Hines

Group Art Unit
1645



☒ Responsive to communication(s) filed on Dec 14, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 10-20 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 10-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on December 14, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/900,559 is acceptable and a CPA has been established. An action on the CPA follows.

Amendment Entry

2. The amendment filed December 14, 2000 has been entered. Claims 10 and 20 have been amended. Claims 1-9 have been canceled. Claims 10-20 are pending in this Office Action

Drawings

3. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 10-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 10 and 20 have been amended to describe an assay chamber which is separate from the lateral flow immunochromatographic device. However applicant has not pointed to support in the specification for support of this amendment. Therefore, the amendment will be considered new matter.

Response to Arguments

5. Applicant's arguments filed December 14, 2000 have been fully considered but they are not persuasive.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 10-11, 13-15 and 17-20 is rejected under 35 U.S.C. 102(b) as being anticipated by Imrich et al.(US Patent 5,415,994) is maintained.

Applicant argues that Imrich et al., fails to teach a separate assay chamber separate from the lateral flow immunochromatographic device. However, in figures 2A and 2B Imrich et al., illustrates the separate extraction chamber. It has a proximal bowl joined to the cylindrical

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portion by a circular opening (col. 9 lines 8-13). Samples on the swabs are inserted into the cylindrical portion through the bowl, after the sample-containing swab has been placed in the extraction chamber, the extraction solution may be added to the bowl and then flow into the cylindrical portion, wherein the treated sample may then flow onto the sample receiving zone (col. 9 lines 13-21). The cylindrical portion will often have a stop means to stop the ingress of the sample containing support (col. 4 lines 4-6). The claim requires that the assay or extraction chamber is separate from the device. Imrich et al., teaches a separate and distinct bowl area for extraction to occur and Imrich et al., teaches the use of extraction tubes. Therefore either this bowl area is separate or the extraction tubes are separate from the device and therefore meets the limitations of the claims. Therefore, Imrich et al., teaches an assay chamber which is separate from the lateral flow immunochromatographic device.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imrich et al., in view of Bogart et al., is maintained. Imrich et al., has been discussed above.

Applicant argues that Imrich et al., in view of Bogart et al., fails to teach a separate assay chamber separate from the lateral flow immunochromatographic device. In response, Imrich et al.,

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has been discussed above, and it has been shown that Imrich et al., teaches a separate chamber. However, Bogart et al., also discuss a separate chamber. Bogart et al., states that assay kits including separate extraction reagents in bottles can deliver the extraction solution into a sample tube (col. 1 lines 34-36). Bogart et al., teaches methods which comprises extraction materials being contained in micro tubes (col. 1 lines 58-60). Other kits disclosed also teach separate extraction tubes (col. 6 lines 19-25). The test procedure section teaches adding drops of reagent 1 are add to the extraction tube (step 4); the swab can stand in the solution (step 5); add reagent 1B (step 6); use the swab to mix the reagent 2 with extraction solution (step 7); discard the swab and retain the contents of the tube (step 8); add reagent 3 and mix thoroughly either with a vortex or by shaking the tube (step 9); and transfer solution onto the test device (step 10). (col. 15 lines 3-35). Therefore, it would have been obvious to one of ordinary skill in the art to optimize the experimental parameters and reagents and previously known separate assay chambers as taught by Bogart et al., using a method of determination including a separate assay chamber as taught by Imrich et al., by selecting such conventional components for generating nitrous acid and times of extraction as taught by Bogart et al., where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill.

9. Applicant again refers to the Declaration of Richard H. Schwartz under 37 CFR 1.132 filed May 10, 1999. However the Declaration is still insufficient to overcome the rejection of claims 10-20 based upon Imrich et al., alone or in combination with Bogart et al., because it refers

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to OSOMTM system and not to the individual claims of the instant application. The declaration makes references to the OSOMTM's overall sensitivity, however those features are not relevant to the claims of the instant application. There is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MEP. § 716. Therefore, again, the Schwartz Declaration is not persuasive.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

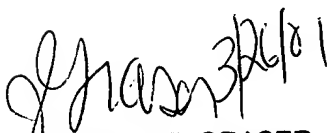
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines



March 26, 2001



JENNIFER E. GRASER
PRIMARY EXAMINER